UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA), INC. et al., Defendants.	:	Civil Action No. 17-13476 (SRC) **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiff Impax Laboratories, Inc. ("Impax") and Defendants Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA), Inc. (collectively, "Zydus"). In this patent infringement suit involving a pharmaceutical patent, the parties seek construction of a claim term in U.S. Patent No. 9,089,608 ("the '608 patent").

The parties dispute the construction of the term "a controlled release oral solid formulation of levodopa" in claim 21, which states:

> A controlled release oral solid formulation of levodopa having a median levodopa plasma or serum concentration profile comprising:
>
> a. a time of administration;
>
> b. a first concentration at a first time, that occurs within one hour of said time of administration;
>
> c. a second concentration at a second time, that occurs after said first time;

d. a third concentration at a third time, that occurs at least four hours after said second time;

wherein said second concentration is equal to the maximum concentration of said profile; said first concentration is equal to about fifty percent of said second concentration; said third concentration is equal to about fifty percent of said second concentration.

Plaintiff contends that the term has its ordinary meaning and does not need construction.

Zydus contends that the term should be construed as follows:

A controlled release oral solid formulation of levodopa that contains

(a) a controlled release component comprising a mixture of levodopa, a decarboxylase inhibitor and a rate controlling excipient;

(b) an immediate release component comprising a mixture of levodopa and a decarboxylase inhibitor; and

(c) a carboxylic acid component that is a distinct component (i.e. freely separable)."

At the outset, the Court observes that, in claim 21, the term appears only in the preamble. Zydus argues as if the preamble term limits the claim, but never makes that argument. "Generally, the preamble does not limit the claims." Georgetown Rail Equip. Co. v. Holland L.P., 867 F.3d 1229, 1236 (Fed. Cir. 2017). Zydus is surely aware of the body of Federal Circuit law which allows exceptions to this general rule, but does not argue that the term falls within any of them.

Instead, Zydus argues that this Court should limit claim 21 based on a prosecution disclaimer found in a different patent in another case. In Impax Labs., Inc. v. Actavis Labs. FL, Inc., 2017 U.S. Dist. LEXIS 70295, at *20 (D.N.J. May 9, 2017) ("Impax 2017"), this Court construed the term "distinct component" in various claims in U.S. Patent No. 8,377,474 (the "'474 patent") and found that, during prosecution, the applicants had made statements which

clearly and unequivocally disavowed certain territory within the scope of that term.

In the instant case, neither the word "distinct" nor the term, "distinct component," appears in claim 21. Zydus argues as if, in claim construction, meaning may be freely separated from the words which generated it, and can then be pasted on someplace else, such as another patent in another case. Zydus has not explained how this is possible under Federal Circuit law.[1] In Impax 2017, this Court found that the applicants for the '474 patent, during prosecution, made disclaiming statements which narrowed the scope of the meaning of the term, "distinct component." Zydus has failed to show that this has any relevance to the present question, which is the meaning of the term, "a controlled release oral solid formulation of levodopa."

Zydus argues as if a judicial finding of prosecution disclaimer attaches to the patent and then spreads to every limb and leaf in the family patent tree. It is not so. Zydus has failed to show that its proposed construction has any basis in Federal Circuit law. Zydus quotes the relevant Federal Circuit principle, but seems to misconstrue it: "when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered." Biogen Idec, Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090, 1095 (Fed. Cir. 2013). This legal principle concerns the scope of the meaning of particular claim terms: it requires that "the patentee unequivocally and unambiguously disavow[] a certain meaning to obtain a patent." The fact that the applicants unequivocally and unambiguously disavowed a certain meaning of the term, "distinct component," during prosecution of the '474 patent, ***cannot***,

[1] Zydus claims that the claims in the '474 patent also contained the term, "a controlled release oral solid formulation of levodopa." While this is correct, this Court did not construe that term in Impax 2017.

without more, constitute an unequivocal and unambiguous disavowal of a certain meaning of the entirely different term, "a controlled release oral solid formulation of levodopa," in the '608 patent.

In support, Zydus also cites Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999), but here is what the Federal Circuit held in that case: "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." "Distinct component" is not the same claim limitation as "a controlled release oral solid formulation of levodopa."

The Court concludes that Plaintiff is correct and that the phrase, "a controlled release oral solid formulation of levodopa," has its ordinary meaning.

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: July 25, 2019